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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,108	08/22/2003	Meir Rosenberg	022719-0045	8437

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NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
08/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/646,108	ROSENBERG, MEIR	
	Examiner	Art Unit	
	HELEN NGUYEN	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8-15,17-24,26-30,32,33 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,8-15,17-24,26-30,32,33 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/29/2009 has been entered.

2. Claims 1, 22, and 29 are amended. Claims 36-44 are new. **Claims 1, 3-4, 8-15, 17-24, 26-30, 32-33, and 36-44** remain pending and under prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1, 3-4, 8-10, 15, 17-18, 21-24, 28-30** rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks (US Pat No. 4711249) in view of Bobo, Sr, (US Pat No. 5573007), further in view of Wallace et al (US Pat No. 5951497), and even further in view of Milder et al (US Pat No. 5116305).

5. In regard to **Claims 1, 22, and 29**, Brooks discloses a pressure sensor device comprising: an elongate catheter 10 including a fluid-filled 38, fluid-impermeable, permanently sealed lumen

28 filled with an incompressible fluid (i.e. saline) extending between a distal flexible membrane 35 that is disposed extending across an opening formed in the sidewall of the catheter and is adapted to be exposed to an external pressure source and a proximal pressure sensor 40 disposed across an open proximal end of the catheter that is effective to measure pressure of the external pressure source in response to displacement of the pressure-sensitive component (Col.4: 1-6), best seen in Figure , wherein Brooks disclose using said pressure sensor device for use in coronary arteries and thus must be implanted within a patient's ventricle for direct pressure readings (Col.1: 15-16). It is noted that the recitation of the flexible membrane being "spray coated" constitutes a product by process recitation wherein it is only necessary that the structure be present. See MPEP 2113 [R-1].

6. However, Brooks does not disclose the invention with a lumen adapted to accommodate fluid flow therethrough and in fluid communication with a plurality of fluid-entry ports formed in the elongate catheter. Bobo, Sr teach an analogous device comprising a fluid lumen as well as at least one working lumen 50a,b to effectively permit fluid flow for infusion/withdrawal of liquids or other substances through the catheter, best seen in Figure 3c (Col.3: 28-34). Wallace et al also teach an analogous device comprising a lumen 332 adapted to accommodate fluid flow with a plurality of fluid entry ports 332a to effectively provide multiple access to the lumen in case of clogging, best seen in Figure 16 (Col.17: 37-42).

7. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brooks such that there is a separate lumen adapted to accommodate fluid flow therethrough and in fluid communication with a plurality of fluid-entry ports formed in the elongate catheter as taught by Bobo, Sr and Wallace et al respectively,

to effectively enable permit fluid flow for infusion/withdrawal of liquids or other substances through the catheter and more than one access point in case of clogging.

8. However, Brooks, Bobo, Sr, and Wallace et al do not specify the compliance of the flexible membrane. Milder et al teach that a flexible balloon membrane has a compliance of 0.05 cm^3/mmHg (Col.5: 42-56) and can change relative to volume, instead of a flexible membrane with a compliance in the range of 0.05μL/mmHg to 2μL/mmHg as disclosed by the applicant. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a flexible membrane with a compliance of 8μL/mmHg because Applicant has not disclosed that a membrane with a compliance in the range of 0.05μL/mmHg to 2μL/mmHg provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Milder et al.'s membrane and the Applicant's invention, to perform equally well with either the compliance as taught by Milder et al or the claimed membrane compliance of 0.05μL/mmHg to 2μL/mmHg, when taking into account the membrane volume of Brooks as modified by Bob, Sr, and Wallace et al, because both would perform the same function of causing a shift in equilibrium, with little force, and transferring the pressure signal to the sensor.

9. In regard to **Claims 3 and 23**, Brooks discloses the flexible membrane 35 is disposed at a distal end of the second lumen 28, best seen in Figure 1, and the pressure sensor 40 is coupled to a proximal end of the second lumen, best seen in Figure 1.

10. In regards to **Claim 4**, Brooks discloses the flexible membrane 35 includes a first surface in contact with fluid within the second lumen, and a second, opposed surface adapted to be exposed to an external pressure source, best seen in Figure 1.

11. In regard to **Claims 24 and 30**, Brooks discloses the opening is formed in the sidewall of the catheter, best seen in Figure 1.

12. In regards to **Claim 9**, Brooks discloses the second lumen 28 contains a predetermined volume of fluid.

13. In regards to **Claim 10**, Brooks discloses the second lumen 28 is free of voids.

14. In regards to **Claim 15**, Wallace et al disclose the second lumen has a diameter that is less than a diameter of the first lumen (Col.4: 20-24).

15. In regards to **Claim 17**, Brooks discloses the catheter 10 has a compliance that is less than a compliance of the flexible membrane 35.

16. In regards to **Claim 18**, Brooks discloses the catheter 10 has a low compliance such that it is not susceptible to deformation as a result of exposure to the external pressure source.

17. In regard to **Claims 21 and 28**, Brooks discloses the flexible membrane 35 comprises a flexible sleeve that is formed around a distal end of the catheter and that is in fluid communication with the second lumen 25, best seen in Figure 1.

18. In regards to **Claim 8**, Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the invention above but do not disclose the flexible membrane formed of a material selected from the group consisting of polyurethane, silicone, and solvent-based polymer solutions. However, Wallace et al disclose do disclose that said flexible membrane is made of an elastomer (Col.9: 59-62) and that one example of an elastomer is polyurethane (Col.8: 65-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the flexible membrane of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al out of an elastomer such as polyurethane as taught by Wallace et al as an effective material for transmitting the pressure readings.

19. **Claim 14** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks, Bobo, Sr, Wallace et al, and Milder et al, further in view of Sgourakes (US Pat No. 4638656).

20. Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the fluid in the second lumen above but do not disclose its kinematic viscosity. Sgourakes teaches a differential pressure transmitter 20 comprising a first and second lumen, 22 and 24, fluid-filled region 50, and flexible membranes 42 and 44. The viscosity of the fill-liquid in the fluid filled region 50 is 5 cs (column 4, lines 40-45) for the purpose of pressure detection. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to

modify the invention of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al, such that the fluid in the second lumen has a viscosity of 5 cs, as taught by Sgourakes to provide a fluid that accurately detects pressure.

21. **Claims 11, 13, 19, 26-27, and 32-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks, Bobo, Sr, Wallace et al, and Milder et al, further in view of Brockway et al (US Pat No. 4846191).

22. In regards to **Claim 11**, Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the second lumen above but do not disclose the volume of fluid in said lumen or the dimensions of diameter or length. Brockway et al disclose an analogous pressure sensor device comprising a lumen having a diameter in the range of about 0.1 mm to 0.3 mm and a length in the range of about 5 cm to 20 cm (Col.6: 13-16). From these dimensions, Brockway et al teach that the lumen is capable of holding 3 μL of fluid, which in the range of about 1 μL to 10 μL. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the diameter and length of the second lumen of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al, in the range of about 0.1 mm to 0.3 mm and 5 cm to 20 cm respectively, such that the volume of fluid contained is in the range of about 1 μL to 10 μL as taught by Brockway et al, as an effective dimension for the desired use.

23. In regard to **Claims 13, 26, and 32**, Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the fluid in the second lumen above but do not disclose said fluid as

biocompatible and with a low viscosity. It is noted that Brooks discloses the fluid is saline which is known to possess low viscosity and is also biocompatible (Col. 3: 15-17). Brockway et al disclose an analogous pressure sensor device comprising a lumen 28 filled with a biocompatible low viscosity fluid 29 to effectively obtain pressure readings (Col.5: 24-34). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the fluid in the second lumen of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al to be biocompatible and have a low viscosity as taught by Brockaway et al as an effective means to transmit the pressure for accurate readings and prevent harmful reactivity with the body in case of leakage respectively.

24. In regard to **Claims 19, 27, and 33**, Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the pressure sensor above but do not disclose the sensor having a frequency response that is greater than 20 Hz. Brockway et al disclose an analogous pressure sensor device with a pressure sensor having a frequency response at greater than 20 Hz (Col.6: 30-37) as an effective response frequency for measuring pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pressure sensor of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al have a frequency response that is greater than 20 Hz as taught by Brockway et al as an effective response frequency for measuring pressure.

25. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al, further in view of Cosman (US Pat No. 4385636).

26. Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the second lumen with fluid above, wherein the fluid is saline which is known to possess low viscosity, but do not disclose the fluid is silicone fluid. Cosman teaches that silicone fluid is effectively used to transmit pressure (Col.14: 18-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the low viscosity fluid of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al to be a silicone fluid as taught by Cosman as an effective fluid to transmit pressure for accurate readings.

27. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks, Bobo, Sr, Wallace et al, and Milder et al, further in view of Mann et al (US Pat No. 20040167580).

28. Brooks in combination with Bobo, Sr, Wallace et al, and Milder et al disclose the pressure sensor above but do not disclose the range of compliance of said sensor. Mann et al teach that a pressure sensor with a low compliance is desirable to prevent errors in sensed pressure readings (¶0156) but do not explicitly state a value for said compliance. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the pressure sensor with a compliance in the range of about 0.1μL/mmHg to 0.02μL/mmHg because Applicant has not disclosed that a pressure sensor with such a specific compliance provides an advantage, is used for a particular purpose, or solves a stated problem, other than that a low compliance is desirable just as Mann et al teach. One of

ordinary skill in the art, furthermore, would have expected the pressure sensor of Mann et al and the Applicant's invention, to perform equally well in the function of pressure sensing as both disclose measuring pressure with a sensor of low compliance. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pressure sensor of Brooks as modified by Bobo, Sr, Wallace et al, and Milder et al to have a low compliance as taught by Mann et al, such as the range of 0.1μL/mmHg to 0.02μL/mmHg.

29. **Claims 36, 38-39, and 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks in view of Bobo, Sr and Wallace et al.

30. Brooks discloses a pressure sensor device comprising: an elongate catheter 10 including a fluid-filled 38, fluid-impermeable, permanently sealed lumen 28 filled with an incompressible fluid (i.e. saline) extending between a distal flexible membrane 35 that is disposed extending across an opening formed in the sidewall of the catheter and is adapted to be exposed to an external pressure source and a proximal pressure sensor 40 disposed across an open proximal end of the catheter that is effective to measure pressure of the external pressure source in response to displacement of the pressure-sensitive component (Col.4: 1-6), best seen in Figure , wherein Brooks disclose using said pressure sensor device for use in coronary arteries and thus must be implanted within a patient's ventricle for direct pressure readings (Col.1: 15-16). It is noted that the recitation of the flexible membrane being "spray coated" constitutes a product by process recitation wherein it is only necessary that the structure be present. See MPEP 2113 [R-1].

31. However, Brooks does not disclose the invention with a lumen adapted to accommodate fluid flow therethrough and in fluid communication with a plurality of fluid-entry ports formed

in the elongate catheter. Bobo, Sr teach an analogous device comprising a fluid lumen as well as at least one working lumen 50a,b to effectively permit fluid flow for infusion/withdrawal of liquids or other substances through the catheter, best seen in Figure 3c (Col.3: 28-34). Wallace et al also teach an analogous device comprising a lumen 332 adapted to accommodate fluid flow with a plurality of fluid entry ports 332a to effectively provide multiple access to the lumen in case of clogging, best seen in Figure 16 (Col.17: 37-42).

32. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Brooks such that there is a separate lumen adapted to accommodate fluid flow therethrough and in fluid communication with a plurality of fluid-entry ports formed in the elongate catheter as taught by Bobo, Sr and Wallace et al respectively, to effectively enable permit fluid flow for infusion/withdrawal of liquids or other substances through the catheter and more than one access point in case of clogging.

33. **Claim 37** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks, Bobo, Sr, and Wallace et al, further in view of Sgourakes.

34. Brooks in combination with Bobo, Sr, and Wallace et al disclose the fluid in the second lumen above but do not disclose its kinematic viscosity. Sgourakes teaches a differential pressure transmitter 20 comprising a first and second lumen, 22 and 24, fluid-filled region 50, and flexible membranes 42 and 44. The viscosity of the fill-liquid in the fluid filled region 50 is 5 cs (column 4, lines 40-45) for the purpose of pressure detection. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the invention

of Brooks as modified by Bobo, Sr, and Wallace et al, such that the fluid in the second lumen has a viscosity of 5 cs, as taught by Sgourakes to provide a fluid that accurately detects pressure.

35. **Claim 40** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks, Bobo, Sr, and Wallace et al, further in view of Brockway et al.

36. Brooks in combination with Bobo, Sr, and Wallace et al disclose the pressure sensor above but do not disclose the sensor having a frequency response that is greater than 20 Hz. Brockway et al disclose an analogous pressure sensor device with a pressure sensor having a frequency response at greater than 20 Hz (Col.6: 30-37) as an effective response frequency for measuring pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pressure sensor of Brooks as modified by Bobo, Sr, and Wallace et al have a frequency response that is greater than 20 Hz as taught by Brockway et al as an effective response frequency for measuring pressure.

37. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brooks, Bobo, Sr, and Wallace et al, further in view of Mann et al.

38. Brooks in combination with Bobo, Sr, and Wallace et al disclose the pressure sensor above but do not disclose the range of compliance of said sensor. Mann et al teach that a pressure sensor with a low compliance is desirable to prevent errors in sensed pressure readings (¶0156) but do not explicitly state a value for said compliance. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the pressure sensor with a compliance in the range of about

0.1μL/mmHg to 0.02μL/mmHg because Applicant has not disclosed that a pressure sensor with such a specific compliance provides an advantage, is used for a particular purpose, or solves a stated problem, other than that a low compliance is desirable just as Mann et al teach. One of ordinary skill in the art, furthermore, would have expected the pressure sensor of Mann et al and the Applicant's invention, to perform equally well in the function of pressure sensing as both disclose measuring pressure with a sensor of low compliance. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the pressure sensor of Brooks as modified by Bobo, Sr, and Wallace et al to have a low compliance as taught by Mann et al, such as the range of 0.1μL/mmHg to 0.02μL/mmHg.

Response to Arguments

39. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736